

SEP 29 2005

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

NEW DEVICE NAME: VICRYL* Mesh Bag

PREDICATE DEVICES NAME: VICRYL Mesh

Device Description

VICRYL Mesh Bag consists of a VICRYL Mesh adapted to the form and size of kidney, spleen, or liver and tied with VICRYL sutures (dyed and undyed).

The integrated strands of VICRYL sutures are threaded along the periphery of the mesh, which facilitates its use as organ support for the kidney, spleen, or liver. The VICRYL Mesh is prepared from polyglactin 910, a synthetic absorbable copolymer of glycolide and lactide, derived respectively from glycolic acid and lactic acids. The mesh is prepared from uncoated, undyed fiber identical in composition to that used in VICRYL (polyglactin 910) synthetic absorbable suture, which has been found to be inert, nonantigenic, and nonpyrogenic and to elicit only a mild tissue reaction during absorption.

Intended Use

VICRYL Mesh bag may be used wherever temporary wound or solid organ support is required (kidney, liver, spleen).

Indications Statement

VICRYL Mesh bag may be used wherever temporary wound or solid organ support is required (kidney, liver, spleen).

Technological Characteristics

VICRYL Mesh Bag has similar technological characteristics as the predicate device. The VICRYL Mesh Bag is essentially VICRYL Mesh that has been preshaped to specific sizes to facilitate its application.

Performance Data

Prior data supporting the predicate device demonstrate that VICRYL Mesh Bag performs as intended.

Conclusions

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Devices under the Federal Food, Drug, and Cosmetic Act.

Contact

Jennifer Paine
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908-218-3323



SEP 29 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jennifer M. Paine, M.S.
Manager, Regulatory Affairs
Ethicon, Inc.
Route 22 West
Somerville, New Jersey 08876

Re: K051701
Trade/Device Name: VICRYL Mesh Bag
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: August 26, 2005
Received: August 29, 2005

Dear Ms. Paine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051701

Indications for Use

510(k) Number (if known): K051701

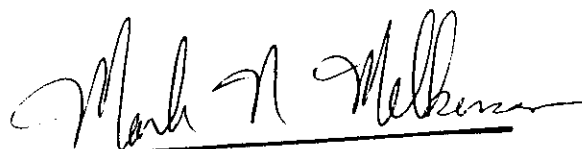
Device Name: VICRYL Mesh Bag

Indications for Use:

VICRYL Mesh bag may be used wherever temporary wound or solid organ support is required (kidney, liver, spleen).

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number

K051701

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